

Appl. No.: 10/780,296  
Amdt. dated 11/15/2006  
Reply to Office action of July 20, 2006

### **REMARKS/ARGUMENTS**

Claims 1-8 and 12-18 are pending in the subject application. Claims 1-8 and 12-18 presently stand rejected. Claims 1, 8, 13, 16, and 17 have been amended by the present amendment. New claims 19 and 20 have been added by the present amendment. No new matter is added. Therefore, upon entry of the present amendment, claims 1-8 and 12-20 will remain pending in the subject application. Reexamination and reconsideration of the claims are respectfully requested in view of these amendments and the following remarks. The Examiner's comments in the Office Action are addressed below in the order set forth therein.

#### **Interview Summary**

A telephonic interview in the above-referenced matter occurred on October 20, 2006, between Examiner Mark L. Berch and Applicants' Representative, Jeffrey W. Childers. Applicants thank the Examiner for his time and consideration in conducting the interview. Examiner Berch prepared an Interview Summary describing the substance of the interview. In the Interview Summary, Examiner Berch indicated that the proposed amendment was reviewed and that it would overcome all rejections. Examiner Berch also indicated that several species in claim 17 has "sulfonyoxy" and it would be likely that sulfo was actually intended. Applicants respectfully submit that the present Amendment and Remarks are consistent with the substance of the telephonic interview.

#### **The Rejection of Claims 1-4, 12-14, and 18 under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn**

Claims 1-4, 12-14, and 18 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More particularly, the Office Action asserts that in the A' definition in claim 1, O and S are now impossible because a 6-membered heteroaromatic ring cannot contain either O or S.

Applicants have amended claim 1 and claim 13 by removing O and S from the definition of A' and by clarifying that A' can be a 6-membered aromatic ring or a heteroaromatic ring

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containing 1 to 4 nitrogen atoms. Applicants respectfully submit that claim 1 and claim 13 are in condition for allowance and respectfully request the same. Claims 2-4, and 12 depend from claim 1, and claims 14 and 18 depend from claim 13. Because claims 1 and 13 are believed to be in condition for allowance, dependent claims 2-4, 12, 14 and 18 also are believed to be in condition for allowance and Applicants respectfully request the same.

The Rejection of Claims 1-7,12-16, and 18 under 35 U.S.C. § 112, First Paragraph,  
Should Be Withdrawn

Claims 1-7, 12-16, and 18 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action lists four points (A-D) for rejecting the claims. Each point is addressed below in the order it appears in the Office Action:

A. The Office Action asserts that the removal of “it denotes” from the R<sub>6</sub> definition introduces new matter by changing its role. Applicants have amended claim 1 and claim 13 by inserting the phrase “it denotes” immediately preceding the term “—(CH<sub>2</sub>)<sub>m</sub>—NHCOOR<sub>8</sub>.” The portion of claim 1 in question has now been returned to its original form and claim 13 has been amended to be consistent with the language of claim 1 as originally filed. Accordingly, Applicants submit that the present amendment renders moot the rejection of claim 1 and claim 13 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement and respectfully request that the rejection of claim 1 and claim 13 as it relates to the phrase “it denotes” be withdrawn at this time.

B. The Office Action asserts that the amino substituted by C<sub>1-8</sub> is new matter. Applicants have amended claim 1 and claim 13 by deleting the reference to “amino substituted with C<sub>1</sub>-C<sub>8</sub> alkyl....” Applicants submit that the present amendments render moot the rejection of claim 1 and claim 13 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement and respectfully request that the rejection of claim 1 and

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claim 13 as it relates to the phrase “amino substituted with C<sub>1</sub>-C<sub>8</sub> alkyl” be withdrawn at this time.

C. The Office Action asserts that the inclusion of R<sub>8</sub> into the definition list for R<sub>6</sub> expands the definition of R<sub>8</sub> and allegedly is new matter. Applicants have amended claim 1 and claim 13 by defining R<sub>8</sub> as it was defined in the claims as originally filed. Support for this amendment can be found on page 9 of the application as filed and in original claim 1. No new matter has been added. Applicants respectfully submit that the present amendments render moot the rejection of claims 1 and 13 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement and respectfully request that the rejection of claim 1 and claim 13 as it relates to the definition of R<sub>8</sub> be withdrawn at this time.

D. The Office Action asserts that the new choice of R<sub>4</sub> as COOH is allegedly new matter. Without acquiescing to the Examiner’s comments, Applicants have amended claims 1, 13, and 16 by deleting the variable “COOH” from the definition of R<sub>4</sub> therein. Applicants also have amended claim 17 by deleting reference to the compound named 8-benzyl-3-[2-(3-carboxyphenyl)ethyl]-1-propylxanthine, in which R<sub>4</sub> is COOH. Accordingly, Applicants submit that the present amendments render moot the rejection of claims 1, 13, and 16 as allegedly failing to comply with the written description requirement and respectfully request that the rejection of claims 1, 13, and 16 as it relates to the choice of R<sub>4</sub> as COOH be withdrawn at this time.

Applicants submit that claims 1, 13, 16, and 17 as currently amended are in condition for allowance and respectfully request the same. Because claims 1 and 13 are believed to be in condition for allowance, dependent claims 2-7, 12, 14-15, which depend from claims 1 and 13, also are believed to be in condition for allowance and Applicants respectfully request the same.

The Rejection of Claims 1-8 and 12-18 under 35 U.S.C. § 112, First Paragraph,  
Should Be Withdrawn

Claims 1-8 and 12-18 have been rejected under 35 U.S.C. § 112, first paragraph, under the contention that the specification allegedly does not provide enablement for hydrates.

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Without acquiescing to the Patent Office's contention, Applicants have amended claims 1, 8, 13, and 17 by deleting the term "hydrates" therefrom. Applicants reserve the rights to file one or more continuation applications directed to the subject matter deleted from claims 1, 8, 13, and 17. Applicants respectfully submit that the present amendments render moot the rejection of claims 1-8 and 12-18 under 35 U.S.C. § 112, first paragraph, under the contention that the specification allegedly does not provide enablement for hydrates and request that this rejection be withdrawn.

The Provisional Rejection of Claims 1-8 and 12-18 for Double Patenting

Should Be Withdrawn

Claims 1-8 and 12-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending application serial no. 10/861,677 (hereinafter "the '677 application) for the reasons stated in the Office Action. Without acquiescing to the grounds of the double patenting rejection, Applicants note that the copending applications are still in the process of examination. Thus, it is not yet known which of these applications will be the first to be allowed for issuance as a patent. Should the copending '677 application be the first to be in condition for allowance, Applicants will, upon notification to this effect, either argue the double-patenting rejection or timely file a terminal disclaimer in the present application. Applicants therefore respectfully submit that they have responded appropriately to this provisional rejection and request that this rejection be withdrawn at this time.

Clarifying Amendments

During the telephonic interview, the Examiner noted that several species in claim 17 include the prefix "sulfonyoxy" and it would be likely that the prefix sulfo was actually intended. Applicants have amended claim 17 by deleting the letters "noxy" from the prefix "sulfonyoxy." The prefix of the species in question now reads "sulfo," for example, "-(4-sulfobenzyl)xanthine." Support for this amendment can be found in Examples 10, 16, and 17, each of which discloses a species having an "-SO<sub>3</sub>H" substituent group. Applicants respectfully submit that one of

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ordinary skill in the art would recognize that an “ $-SO_3H$ ” substituent group would be named a “sulfo” group. Indeed, the International Union of Pure and Applied Chemistry (IUPAC) recommends that the prefix for the group “ $-SO_3H$ ” should be referred to as “sulfo.” See *Nomenclature of Organic Chemistry, Sections A, B, C, D, E, F, and H*, Rigaudy, J. and Klesney, S. P., eds., Pergamon Press, Oxford, 1979. Accordingly, Applicants respectfully submit that claim 17 is in condition for allowance and respectfully request the same.

#### New Claims

New claims 19 and 20 have been added by the present amendment. New claims 19 and 20 are directed to the compound 8-benzyl-3-[2-(3-carboxyphenyl)ethyl]-1-propylxanthine; 3-[2-(2-carboxyphenyl)ethyl]-8-(3-fluorobenzyl)-1-propylxanthine; 3-[2-(2-carboxyphenyl)ethyl]-8-(3-nitrobenzyl)-1-propylxanthine; 3-[2-(2-carboxyphenyl)ethyl]-1-propyl-8-[(2-pyridyl)methyl]xanthine; and 3-[2-(2-carboxyphenyl)ethyl]-1-propyl-8-[(2-pyridyl)methyl]xanthine and a composition of said compounds in a pharmaceutically acceptable carrier, respectively. Support for new claims 19 and 20 can be found in pages 11-12, and Example 12, pages 27-28, of the application as filed and in original claims 9 and 12. No new matter has been added. Applicants submit that new claims 19 and 20 are in condition for allowance and respectfully request the same.

#### CONCLUSION

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. §112, first paragraph, and §112, second paragraph, are now overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of

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this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

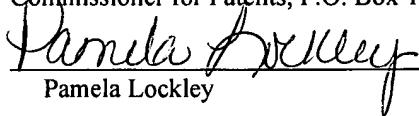


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I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
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